

11/18/94

To: Gene Stein
at Wachtel Lipton

M E M O R A N D U M

From: John Mulderig

FYI & Slade
deposition.

VIA FACSIMILE

TO: Bernard V. O'Neill
FROM: William E. Hoffmann, Jr.
W. Randall Bassett
DATE: December 20, 1993
RE: Nicotine Dependence Conference

On November 11-14, 1993, we attended the American Society of Addiction Medicine Sixth National Nicotine Dependence Conference, Atlanta. This memorandum summarizes the presentations that we attended. While attending the conference, we learned that ABC television was filming portions of the conference for a segment on its news show "Day One." We did not learn when the segment will air.

I. Regulating Tobacco Products; John Slade, M.D.; ASAM Conference Chairman; St. Peter's Medical Center and Robert Wood Johnson Medical School.

Slade first noted that tobacco products were virtually unregulated in the United States. He noted that five regulatory agencies exist with power to regulate tobacco: the ATF, FTC, FDA, Justice Department, and Consumer Products Safety Commission. Each of these agencies, according to Dr. Slade, has been inadequate in their regulation of tobacco.

The Consumer Products Safety Commission has authority to regulate any product deemed "dangerous". The Commission was petitioned to regulate tobacco as a dangerous product. However, the Commission was expressly prevented by Congress from regulating tobacco.

The ATF takes the most active role in regulating tobacco. Most recently, it has been involved in regulating the use of lotteries in promoting cigarettes. Dr. Slade, however, used the "Winston Weekends" promotion as an example of the lack of strict regulation in this area by the ATF.

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The Justice Department also has authority to regulate advertising, although it has never actively regulated tobacco advertising. Slade suggested that the Justice Department should become involved in regulating tobacco promotion at NASCAR races. He noted that such events have a direct influence on children and allow the tobacco industry millions of dollars of unregulated advertising.

The FDA also has authority to regulate the tobacco industry, according to Slade, as a drug under the Food, Drug and Cosmetic Act which grants the FDA regulatory authority. The FDA does not, however, view ordinary tobacco as a drug. Dr. Slade cited several examples in which the FDA did regulate tobacco products, including the "Premier" cigarette. Dr. Slade advocated that the FDA should take a more active role, noting that it could obtain jurisdiction because current advertising stresses weight control as a benefit to smoking tobacco products. Furthermore, the low tar cigarette is promoted as a "safer" cigarette.

The FTC regulates tobacco advertising, including warning labels on cigarette packages. Dr. Slade noted that the FTC's regulation of tobacco products is woefully inadequate. Dr. Slade targeted warning labels for this portion of his talk. First, he noted that roll-your-own cigarettes are excluded from warning labels. Because roll-your-own cigarettes will become more popular if a higher tax is placed on cigarettes, Dr. Slade noted that warning labels should be required on roll-your-own cigarettes. Dr. Slade also advocated more comprehensive warnings than those required currently. Citing warning labels in Canada and Australia, Dr. Slade advocated a similar comprehensive warning label for cigarettes sold in the United States.

II. Marketing Disease to Latinos; Marilyn Aguirre-Molina, Ed.D.; Robert Wood Johnson Medical School. (Handout attached as Exhibit A)

Dr. Marilyn Aguirre-Molina spoke on the marketing of tobacco and alcohol products to ethnic groups. She disparaged both industries throughout her presentation, referring to them as the "pro-death companies" and "disease promoting companies."

Aguirre-Molina first noted that the Hispanic market is attractive to the tobacco and alcohol industries because (1) Hispanics are a fast-growing demographic group; (2) Hispanics have a young median age (implying that the industries can "hook" Hispanics younger); and (3) Hispanics have been relatively ignored by the tobacco and alcohol industries. Philip Morris and Anheiser Busch are among the top five companies in spending money to market their products to Hispanics.

Aguirre-Molina noted that the tobacco and alcohol industries hire young Hispanics to establish good community relations by funding community projects for young Hispanics. These projects are aimed primarily at improving education within the community. Aguirre-Molina, however, believes the tobacco industry (and Philip Morris especially) has established these projects to get young Hispanics "hooked" on cigarettes. Aguirre-Molina cited the Joe Camel advertising campaign as an example of advertisements toward children, stating that the Joe Camel campaign is an advertisement of "bestiality."

III. Opportunities in Tobacco Litigation; Richard A. Daynard, J.D.; Northeastern University School of Law.

Dennard began by introducing himself and his topic as "using courts to control the tobacco industry and place tobacco companies on the defensive." Dennard discussed the various areas of litigation involving the tobacco industry.

An evolving area of litigation that Dennard believes to be very "promising" involves lawsuits against retail stores selling tobacco products to children. Dennard noted that this type of case is easy to bring. Unlike tobacco companies who "fight lawsuits to the death," retailers will not litigate these cases because tobacco sales are a dispensable piece of their business. Accordingly, Dennard believes that lawsuits against retailers will result in the retailer's decision not to sell tobacco products in that store. In fact, Dennard sells a manual for this type of litigation.

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Dennard then discussed the California case against R.J. Reynolds involving the Joe Camel campaign. Dennard explained that the case was brought by a group of plaintiffs under the California Consumer Protection Act. The California Court of Appeals recently denied Defendant's motion to dismiss and will allow the case to go to trial. Dennard considered this a surprise victory with a potential devastating effect on the tobacco industry because the damages for this type of lawsuit is to disgorge profits.

Finally, Dennard discussed product liability cases. Dennard discussed the Broin case, citing the Miami Herald article regarding Bill Campbell's deposition.

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Dennard discussed the Haines case and Judge Sarokin's opinion. He noted that Judge Sarokin's opinion led the U.S. Attorney's office in Brooklyn to open an investigation of the tobacco industry.

Dennard discussed the propriety of nicotine addiction claims. Although the two recent nicotine addiction cases were unsuccessful, Dennard believes nicotine addiction claims are very promising because (1) the defendants cannot blame the plaintiff for contributing to her injuries and (2) cases could be brought as class actions.

Dennard spoke about ETS cases and specifically about the Butler case. Noting that Butler is set for trial next fall, Dennard believes it is a good case for market share liability. Dennard also commented that this case would be different from other smoking and health cases because the tobacco companies cannot blame the plaintiff for his injuries. Although the tobacco companies may argue that plaintiff could have and should have banned smoking in his barber shop, Dennard noted that the tobacco companies maintain that ETS does not pose a health risk.

IV. The Joe Camel Saga; Paul Fischer, M.D.; Medical College of Georgia.

Fischer spoke about a masked study that he conducted to determine children's recognition of cigarette advertisements, focusing on the Joe Camel campaign. Dr. Fischer developed a game that required children ages 3-6 to match products with logos.

Dr. Fischer's study showed that a child's recognition of Joe Camel to cigarettes was as great as that of Walt Disney to Mickey Mouse. Dr. Fischer concluded that the Joe Camel campaign was aimed at enticing teens to smoke.

Dr. Fischer then discussed at length his litigation with R. J. Reynolds regarding the study. RJR is seeking all files relating to the study and wants to interview the children who participated in the study.

Dr. Fischer closed with the statement that Marlboro man should also be studied because it is the number one cigarette of children smokers.

V. Trends and tobacco use in the United States; Gary A. Giovino, Ph.D., M.S.; CDC Office of Smoking and Health.

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in the United States and focussed on various age, sex, and ethnic groups in this regard. Giovino's handout is attached as Exhibit B.

The 1940s and 50s, the prevalence among males peaked at around 67%. Prevalence among women peaked about 10 years later at approximately 44%.

The CDC's objective is for prevalence to be at or below the 15% level for the population over age 18 by the year 2,000. They project, however, that prevalence will be at about 20%.

The quit ratio is going up for men and women at about the same rate. See page 2 of Exhibit B. Women find it harder to quit. Yet progress for quitting is occurring at a similar rate for men and women.

Among women age 24 or under with a high school education or less, initiation was flat from 1965 through 1985.

Since 1970 there has been no change in the percentage of heavy smokers among smokers.

Quit ratios are higher for whites than for blacks. See page 3 of Exhibit B.

High school senior data show a much sharper decline in smoking for blacks than for whites. See page 5 of Exhibit B. Prevalence is higher among high school dropouts than among high school graduates.

Blacks tend to smoke high tar and nicotine cigarettes and are more likely to smoke menthol cigarettes.

Prevalence is much higher for American Indians than for non-indians.

The greater the education, the lower the prevalence.

Studies show that smoking is a function of negative mood. The more frequently that a mood was reported negative, the more likely the person was to be a smoker.

Among people who are trying to quit, 60% of the light smokers claim that they are unable to do so. Seventy percent of the heavy smokers claim they are unable to do so. Two-thirds to three-quarters of American smokers would like to quit.

Every year about 33% of the smokers will try to quit. About 2½% of the smokers actually quit each year. Sixty-nine percent of smokers believe they could quit. Sixty-five percent of smokers believe that their health is affected by smoking. Seventy-seven percent of smokers believe they could avoid health problems if they quit smoking.

The CDC believes progress is being made toward the decline of smoking in all areas but white adolescents and blue collar workers.

VI. The Evolving Epidemic and How to Manage It; Michael J. Thun, M.D., M.S.; Director of Analytic Epidemiology, American Cancer Society.

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Thun's data covered 1982 through 1999 and the population studied was 1.2 million males. They were interviewed in September of 1982 and filled out a 4-page questionnaire. Deaths were followed through 1988.

Current smokers are dying from all causes at a greater rate than nonsmokers.

As age goes up, the rate ratio goes up then declines from 40 to 85 but the rate difference increases in age until very old age. So it is more risky to smoke, the older one is. The pattern is similar for coronary disease and for lung cancer.

The absolute risk for smoking increases in middle age.

Strategies for quitting in middle age have great potential for decrease in mortality.

A small increase in the amount and duration of smoking results in a marked increase in lung cancer.

Factors other than cigarette smoking are affecting mortality from heart disease to a remarkable degree. Smokers in the 80s, however, have a lower rate of death than heart disease than do nonsmokers in the 60s. This is thought to be attributable to generally healthier life-styles in matters other than smoking.

The increase in lung cancer rates among smokers represents a maturing of the tobacco epidemic because the "peak" smokers are getting older.

VII. ETS: Consequences and Control; Stanton A. Glanz, Ph.D.;
University of California at San Francisco, Department of Medicine
Cardiology Division.

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In 1978 there was no evidence that passive smoking caused lung cancer or heart disease. But in 1978, TI did a survey of attitudes toward smokers and commissioned a 1978 Roper poll that indicated that ETS would be a key issue for the industry.

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Glanz went on to say, however, that it took the public 13 years to figure out that TI was right.

Glanz contends that the EPA report is a seminal event. He went through the major findings of the EPA report and, of course, accepted them by implication. He indicated that the public will be more likely to accept the EPA report than the 1986 Surgeon General's Report, for example, because the public views the Surgeon General as some kind of do gooder nanny figure.

Glanz pointed out that restrictions on smoking in public places and smoking around other individuals will result in a decrease in consumption because of the inconvenience of smoking and the elimination of smoking as an automatic, reflex action during the course of a day.

Much of Glanz's talk focussed on his work on the risk of heart disease from ETS. He has done a paper on the relationship between heart disease and spousal smoking. This paper used a meta-analysis and found a relative risk of 1.3, which is statistically significant, even though some of the studies that were subject to the meta-analysis were not statistically significant. He claims adjustments were made for age and diet. He was very critical of the industry's attacks on meta-analysis. He criticized the industry's attacks by using the example of flipping a coin. He said that the industry claimed meta-analysis was invalid, and you had to look at each individual study. This, he said was like looking to each individual flip of a coin to determine if the coin is "fair" and will come up heads 50% of the time. If you look at each individual flip, you would have to conclude that the coin is not fair.

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Glanz cited studies that had been done on the relationship between ETS and heart disease. According to Glanz, the epidemiology shows that with a very low dose of tobacco smoke through ETS, there is a risk that is not much different from the risk to smokers. Therefore, the epidemiology has been criticized from a dose-response point of view because this does not make sense. Furthermore, the epidemiology has been criticized for failure to eliminate confounders.

In response, Glanz says there are actual tests that support the conclusion that ETS is a risk factor for heart disease, and one does not have to rely upon the epidemiology. These tests are possible because the effect of ETS on the heart is immediate, compared to the effect of ETS on the lungs. Therefore, one can do ETS exposure tests that look at platelet activity. Exposure of nonsmokers to ETS causes sticky platelets. Fifteen minutes of exposure to ETS in a hospital waiting room results in platelets as sticky as those of a person who has smoked two cigarettes. It is thought that there is a very low saturation point for causing sticky platelets. Therefore, a cigarette smoker reaches that saturation point quickly, and additional smoke makes no difference. One inhaling ETS reaches the same saturation point fairly quickly. In short, the reason why risk is high in relationship to the dose is that saturation occurs at low levels.

A similar test was done on New Zealand white rabbits with similar results. Also, these tests showed that the more smoke the rabbits were exposed to, the more fat that was deposited in the arteries. Testing with rats demonstrates that if a person has a heart attack after ETS exposure, the heart attack will be worse.

Glanz contends that passive smoking is the third leading cause of preventable death in the United States.

Glanz attacked TI in a couple of ways. First, Glanz showed an announcement published by TI in restaurant trade magazine that stated that restaurant businesses would drop 30% if restaurants were forced by the government to ban smoking. In fact, for a short time during the 80s, there was such a ban in a city in California. The data show that there was no decrease in the business of the restaurants.

Glanz also stated that when proposition 99 concerning the tobacco tax in California was pending, the tobacco industry contributed an average of \$10,000 to each California legislator, compared to only \$5,000 to each United States legislator.

VIII. A Framework for Tobacco Control Policy; Michael P. Eriksen, Sc.D.; CDC, Office of Smoking and Health.

Eriksen discussed establishing a policy for controlling tobacco products in the United States. He noted that there are six elements of tobacco control: prevention, direct services, clean indoor air, advertising and promotion, economic, product regulation and liability.

Prevention

Eriksen noted that no inroads in preventing teen smoking have occurred, especially with white teens, and that smoking among teens is rising. He attributes this to youth access to tobacco products. Figures calculated by the CDC establish that 79% of all cigarettes purchased by underage smokers are purchased at convenience stores and gas stations. Eriksen believes the Synar amendment likely will have a dramatic impact on preventing teen smoking.

Direct Services

Eriksen noted that cessation and awareness activities were the most important activities of this element. He believes smoking cessation may increase with increased treatment of nicotine addiction through nicotine replacement and additional research into nicotine addiction.

Eriksen also advocated raising the public's awareness of smoking and health risks by focusing on effects of smoking other than lung cancer and cardiovascular disease such as impotence and increased stress.

Clean Indoor Air

Eriksen believes significant strides have been made in the clean indoor area through the EPA study and the increase of limits and bans on workplace smoking. He commented that the EPA study was the single most important event to occur in tobacco control. He advocated increased pressure on politicians to provide more smoke-free environments.

Advertising and Promotion

Eriksen noted that the tobacco industry has changed from advertising to promotion. Currently, the tobacco industry spends an estimated three billion dollars on discounts, give aways, and other promotional activities. In contrast, the tobacco industry

spends between six and eight hundred million dollars in advertising. Eriksen believes tobacco advertising will be further curbed by a recently enacted limit on the tax deductibility of advertising. He advocated more regulation of promotional activities to curb tobacco use.

Economics

Eriksen noted that the tobacco industry is more profitable today than ever before. First, price increases on cigarettes have not been proportional to tax increases on the tobacco industry. Currently, fifty cents of every two dollar sale goes to taxes, providing a \$1.50 in revenue to the company. Furthermore, the amount of revenue for farmers from tobacco farming has decreased dramatically. In 1960, 10.4% of all money made on cigarette sales went to farmers. In 1991, the amount had been reduced to 2.6%, primarily due to overseas farming.

Finally, Eriksen focused on trends in cigarette sales and production. He noted that cigarette exports are rising while consumption in the United States is falling. He noted that the tobacco industry is trying to expand its base in third world countries.

Product Regulation and Liability

Eriksen noted that stronger warning labels should be enacted, citing the labels in Canada and Australia as examples.

IX. Cognitive Improvement through Nicotine: Myth or Reality?
George J. Spilich, Ph.D., Department of Psychology and Behavioral Neuroscience, Washington College, Chester, Maryland. (Handout attached as Exhibit C).

A. Introduction. By way of introduction, Spilich said he was going to make three points.

1. Nicotine has no cognitive enhancement value but a myth that it does has been perpetuated by the cigarette companies.
2. Research that cigarette smoking has a positive cognitive effect is based upon flawed research in two respects: improper control groups and improper choice of tasks.
3. When you use appropriate control groups and appropriate choices of tasks, research shows that cigarette smoking has negative cognitive effects.

B. The myth perpetuated by the tobacco companies.

In support of his first point, Spilich displayed several advertisements from the 40s and 50s and contended that they were intended to show that cigarette smoking had cognitive benefits.

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C. Research on the relationship between smoking and the cognitive function.

1. Historical research. Research that goes back to the 1890s shows that smoking has a negative effect on mental performance. Old research shows that smoking college students are more likely to fail or have incompletes in their courses than nonsmoking college students.

Since the earliest days of systematic research into the effects of tobacco use on mental processes, substantial evidence has supported the position that smoking is not beneficial to mental processes. Early research tended to look at scholarship among collegian or high school smokers and nonsmokers. Evidence to the contrary has primarily been generated in the historically recent period.

2. Criticism of Current Research. Much of the current research which supports the position that tobacco use facilitates mental performance is methodologically flawed in three ways. First, an appropriate control group is not used. The comparison has been between smokers and deprived smokers. It would be more appropriate to compare smokers with nonsmokers.

Second, the types of tasks that have been used to measure cognitive performance have been inappropriate. The tasks have been rapid perception tasks. For example, one task was to tell when a clock jumped ahead by two seconds. Another task was a quick, immediate mathematical calculation.

Third, an over generalization has been made from these tasks. Researchers have suggested that the results concerning these types of cognitive

functions show that the type of cognitive functions we engage in in ordinary life are affected in the same way.

Spilich's criticism seemed to be primarily directed toward a study done by _____ Burton, Wesley & Edwards.

- D. Spilich's Research. Research which employs the proper controls and uses tasks which mirror the cognitive demands of the real world indicates that smoking lowers the available ceiling of intellectual resource.

Spilich used three groups in his study: (1) male and female college student nonsmokers; (2) male and female college student active smokers; and (3) male and female college student deprived smokers (deprived for ten hours). He eliminated heavy drinkers and heavy smokers of illegal substances from his subjects.

Spilich used tasks that he claims more closely mirror real world cognitive tasks than those used in the studies he criticizes. One task was to show the subject an array of angular and rounded letters in a line and ask them to search for a target letter. There was no difference among the three groups. The next task involved working with short-term memory. A set of letters was shown on the screen, the screen would then go blank. The subjects were then asked to remember whether a particular letter was in the set. The nonsmoker performed this task more quickly and most accurately. The active smokers were next and the deprived smokers were last. The negative effects were greater on males. Spilich believes, therefore, that nicotine has a stronger negative effect on the cognitive ability of males than it does on females.

The next task was to have the subjects read a story. The subjects were then tested on their ability to remember the central points of the story and tangential details. The nonsmokers performed better. They focussed on the central points of the story. The deprived smokers and active smokers remembered less about the central points and tended to focus more on the tangential details.

The next task was to play a videogame involving driving a car. The subject had to avoid a rear-end collision with the car ahead of his car. The active smoker had

the greatest number of rear end collisions followed by the deprived smokers and the nonsmokers.

The final task was to play an air traffic control videogame. All three groups began crashing planes as the volume of traffic increased, and there was no difference among them. That is, they all began crashing planes at about the same level of traffic. However, the smokers began bringing in planes faster (that is increasing traffic) than did the nonsmokers.

Spilich believes his studies show that smoking reduces the ceiling of the resource for cognitive functions for complex tasks. Therefore, complex tasks with heavy demands will lead to reduced performance by smokers when compared with the performance of nonsmokers in the same way that computer performance degrades rapidly when memory capacity is exceeded.

Spilich also believes that the patch does not result in a decrease in cognitive functions to the same extent of smoking.

He also cited a study indicating that, after controlling for socioeconomic variables, children of nonsmokers performed better on the California Achievement Test than did children of smokers. Therefore, Spilich concludes that ETS has a negative effect on cognitive function.

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X. A Nicotine Dependence Scale Based on Psychiatric Criteria;
Lirio S. Covey, Ph.D.; Columbia University and the New York State
Psychiatric Institute.

Attached as Exhibit D is an abstract of Dr. Covey's presentation.

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XI. Results from a Population Study of Transdermal Nicotine: Good News and Bad News; C. Tracy Orleans, Ph.D., Fox Chase Cancer Center, Division of Cancer Control, Cheltenham, Pennsylvania.

This presentation concerns the results of a subsidized transdermal nicotine patch program to determine the cost effectiveness of providing such subsidized programs for older individuals. One hundred and four subjects were selected, ages 65-74. Of these 871 were interviewed, and the data were based upon those interviews.

The mean family income was under \$10,000 per year. The cost of the patch to the subject was \$6.00 per month, compared to the full cost of \$150.

Subjects had a mean smoking history of 50 years. Seventy-two had tried to quit at least once. The mean number of cigarettes smoked per day for those who had quit at the end of the program was 24 prior to the beginning of the program. Those who had not quit, were smoking 17 cigarettes per day at the time of their interview.

Forty-two percent smoked while using the patch. Twenty-two percent smoked every day while using the patch. The mean number of cigarettes smoked per day while using the patch was 8. Among the every day smokers, the mean was 12.

Six months after the program was terminated, the self-reported quit rate of the 871 subjects interviewed as 31%. Orleans believes that this is inflated. However, if the real number is only 15% - that is if 50% falsely reported that they had quit - Orleans believes that the program would still have a great cost benefit.

Orleans was very critical of adjunctive treatment being given to the subjects, of the lack of advice given to them when the patch was prescribed and of the unusable nature of the package inserts because of small print and because they were written at a 12-14 grade reading level.

XII. Gender Differences in Effect of Major Depression and Level of Nicotine Addiction on Smoking Cessation Outcome; Lirio S. Covey, Ph.D.; Columbia University and New York State Psychiatric Institute.

This study attempted to determine, by certain characteristics, the success of individuals attempting to quit smoking. In general, it was found that psychiatric rating did not result in a lower quit rate. Among males and females, there were differences.

None of the subjects had suffered from a psychiatric disorder or addictive disease for the last six months. That is, those who had been diagnosed as alcohol dependent had been sober for the previous six months. Thirty-five percent of the subjects suffered from major depression at one time. This is compared with community data that shows a 6-7% number. Twenty-eight percent had suffered from alcoholism or drug dependency, 7% from dysthymia, 3% from general anxiety disorders, and 3% from panic disorders.

In general, men did better than women with regard to the quit rate. Major depression was a significant factor for women, but not for men. With regard to alcohol dependence, there was no significant difference between men and women. That is, subjects who did not have an alcohol disorder had a similar quit rate to those who did. A combination of alcoholism and major depression, however, did have a significant effect on men, but not on women. Men who had a combination of depression in alcohol dependency had a quit rate of 0.

Among women, those who had the more education, had the greater difficulty quitting. There was no difference by education in men.

Black women had a more difficult time quitting than white women. Again, there was no difference among men.

It was more difficult for married women to quit, but there was no difficulty by marriage for men. Being married to a smoker had no effect on either group.

In sum, she found (1) the success rate was slightly higher for men; (2) significant risk factors for failure to quit were major depression and nicotine level; (3) women had a higher vulnerability to risk factors. For men, nicotine level was a risk factor and a combination of major depression and alcoholism was a risk factor. For women, major depression alone was a risk factor. Nicotine level was not a risk factor for women.

Covey believes that nicotine replacement therapy might be effective for men, but perhaps not for women. According to another study, women with major depression were seven times more successful with the patch than with a placebo. Fifty percent who used the patch quit, but only 12.5% who used a placebo quit. Among women without depression, 45% who used the patch quit compared to 29% who used the placebo.

Quit rates were lower in men with high systolic blood pressure, but she said this could be a fluke. She suggested, however, lowering the blood pressure to get a better quit rate.

In men without high blood pressure, use of a placebo produced 16% quit rate and use of clonidine resulted in a 33.3% quit rate.